Remarks

This Response is submitted in response to and is believed to be fully responsive to the Office action dated May 14, 2009, wherein restriction of the claims under 35 U.S.C. § 121 is required by the Office.

Claim Amendments

Claims 2, 12-15, and 17-26 have been amended to correct minor informalities. Claim 27 has been amended to recite "wherein the daily dosage of CB1 receptor antagonist is from [[0.0]]1mg to [[5]]100mg." Support for the amendment can be found, for example, in the originally filed specification at page 14, lines 6-19.

Election/Restriction

The Office contends the claims presently under consideration in the application are independent or distinct. Specifically, the Office requires the Applicants, under 35 U.S.C. § 121, "to elect a single disclosed species from generic (i) CB1 receptor antagonist, for example N-piperidino-5-(4-chlorophently)-1-(2,4-dichlorophently)-4methylpyrazole-3-carboxamide, and (ii) hepatic diseases, for example liver fibrosis..."(O.A., p.2)

Initially, the Applicants note that the pending Application is a national stage entry of a PCT filed under 35 U.S.C. § 371. As such, the Application is entitled to unity of invention practice according to the PCT, not restriction practice. *See* MPEP 1893.03(d). Therefore, the Applicants respectfully traverse the restriction requirement as applied to all claims.

When making a lack of unity of invention requirement, the Office must (1) list the different groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group. *See* MPEP 1893.03(d). The Applicants respectfully request that the Office withdraw the restriction requirement and, if the Office wishes to proceed with a lack of unity action, issue such an action with the appropriate support.

Rule 13.2 states "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or

more of the same or corresponding special technical features." Special technical features are defined as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Rule 13.2. The Applicants respectfully submit that, in the present pending application, the requirement of unity of invention is fulfilled, as the claims all relate to CB1 antagonists and all the recited diseases are treatable by a CB1 anatagonist.

The compounds of formula II have the feature in common that they are CB1 antagonists. *See*, for example, the originally filed specification at pages 11 through 12 and Examples 5 and 6. Thus, there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features (related organic compounds) and a single general inventive concept (CB1 receptor antagonists), as required for Unity of invention.

The hepatic diseases have the process of liver fibrosis in common. *See*, for example, the originally filed specification at page 10, lines 3-9. As such, the Applicants respectfully submit that the diseases of claims 22-26 are "so linked as to form a single inventive concept," as required by Rule 13.1.

Because the restriction requirement is improper, the Applicants do not respond directly to the restriction requirement arguments made by the Office. However, to in order to comply completely with the improper restriction /election requirement of the Office action, the Applicants hereby elect as follows:

Within generic group (i), the Applicants elect N-piperidino-5-(4-chlorophenyl)-1-(2,4-dichlorophenyl)-4methylpyrazole-3-carboxamide, with traverse with regard to the disclosed related organic compounds of generic claim 18.

Within generic group (ii), the Applicants elect alcoholic liver cirrhosis, with traverse.

Thus, claims 21 and 23 are elected with traverse. Claims 2, 15, 17, 18, 19, 20, 22, and 24-28 are generic thereto.

Further, it is noted, that pages 3-4 of the election/restriction requirement incorrectly state that there are claims to products and processes. All claims are directed to methods of treatment.

Accordingly, the Applicants respectfully request reconsideration and withdrawal of the restriction/election requirement within generic group (i) regarding election of a single disclosed

species of organic compounds that are CB1 antagonists, and within group (ii) regarding election of a single disclosed species from generic hepatic diseases.

Extension of Time

The Applicants hereby petition for a 1-month extension of time and the accompanying fee is submitted herewith. The Applicants believe no other fees or petitions are due with this filing. However, should any such fees or petitions be required, please consider this a request therefor and authorization to charge Deposit Account No. 50-4058 as necessary.

Conclusion

The Applicants request that a proper unity of invention requirement be provided, or that the requirement be withdrawn.

If the Office should require any additional information or believes that prosecution of the application may be expedited via a telephone conference, the Office is invited to contact the undersigned attorney.

Respectfully submitted,

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